

DOCKET NO.: ISIS-5239

PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Phillip Dan Cook, et al.

Application No.: 10/628,043

Filing Date: July 25, 2003

For: CARBAMATE-DERIVATIZED NUCLEOSIDES AND OLIGONUCLEOSIDES

Confirmation No.: Not Yet Assigned

Group Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

DATE OF DEPOSIT:

August 27, 2003

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

Elizabeth A. McLoud

TYPED NAME: Elizabeth A. McLoud

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

- ☒ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in § 1.491, before the mailing date

of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

☐ In accordance with § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Certification in Accordance with § 1.97(e) is attached; or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

☐ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

☐ Certification in Accordance with § 1.97(e) is attached;

or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of \$180.00 as set forth in § 1.17(p).

☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

- ☒ Copies of references listed on the attached Form PTO-1449 are enclosed herewith

EXCEPT THAT:

- ☒ In view of the voluminous nature of reference 6, and the likelihood that this reference is available to the Examiner, copies are not enclosed herewith.

- ☒ In accordance with § 1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application:

- ☒ Copies of references **1-92 and 96-98** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No. **08/713,742**, filed **September 13, 1996** now **Issued Patent No. 6,111,085**; copies of references **93 and 94** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No. **09/688,394**, filed **October 16, 2000** now **Issued Patent No. 6,322,987**.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

- ☐ The relevance of those listed references which are not in the English language is as follows:
- ☒ There are no listed references which are not in the English language.

Date: August 27, 2003

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Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office		Docket No. ISIS-5239	Application No. 10/628,043
		Applicant Phillip Dan Cook, et al.	
		Filing Date July 25, 2003	Group Not Yet Assigned
		Confirmation No. Not Yet Assigned	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	1	Asseline et al., "Nucleic acid-binding molecules with high affinity and base sequence specificity: Intercalating agents covalently linked to oligodeoxynucleotides", <i>Proc. Natl. Acad. Sci. USA</i> , 1984 , <i>81</i> , 3297-3301	
	2	Atherton et al., "The Fluorenylmethoxycarbonyl Amino Protecting Group", <i>The Peptides</i> , Chapter 1, Gross and Meienhofer (eds.), Academic Press, New York, 1983 , 9, 1-38	
	3	Beaucage et al., "Advances in the Synthesis of Oligonucleotides by the Phosphoramidite Approach", <i>Tetra. Letters</i> , 1992 , <i>48</i> , 2223-2311	
	4	Bennett et al., "Cationic Lipids Enhance Cellular Uptake and Activity of Phosphorothioate Antisense Oligonucleotides", <i>Mol. Pharmacol.</i> , 1992 , <i>41</i> , 1023-1033	
	5	Chollet, "Selective Attachment of Oligonucleotides to Interleukin 1 β and Targeted Delivery to Cells", <i>Nucleosides & Nucleotides</i> , 1990 , <i>9</i> (7), 957-966	
*	6	Cohen, <i>Oligonucleotides: Antisense Inhibitors of Gene Expression</i> , CRC Press, Inc., Boca Raton, Florida, 1989	
	7	Corey et al., "Sequence-Selective Hydrolysis of Duplex DNA by an Oligonucleotide-Directed Nuclease", <i>J. Am. Chem. Soc.</i> , 1989 , <i>111</i> , 8523-8525	
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	9	Delgado et al., "The Uses and Properties of PEG-Linked Proteins", <i>Critical Rev. in Therap. Drug Carrier Systems</i> , 1992 , <i>9</i> (3,4), 249-304	
	10	DeVos et al., "Solid Phase Non Isotopic Labelling of Oligodeoxynucleotides Using 5'-Protected Aminoalkyl Phosphoramidites: Application to the Specific Detection of Human Papilloma Virus DNA", <i>Nucleosides & Nucleotides</i> , 1990 , <i>9</i> (2), 259-273	
EXAMINER		DATE CONSIDERED	

* A copy of this reference will not be forwarded to the U.S. Patent and Trademark Office since it is believed to be too voluminous to send and easily obtainable by the Examiner.



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	11	Dreyer et al., "Sequence-specific cleavage of single-stranded DNA: Oligodeoxynucleotide-EDTA Fe(II)", <i>Proc. Natl. Acad. Sci. USA</i> , 1985 , 82, 968-972	
	12	Gottikh et al., "Synthesis of Oligonucleotides Containing a Carboxyl Group at Either Their 5' End or their 3' End and Their Subsequent Derivatization by an Intercalating Agent", <i>Tetra. Letters</i> , 1990 , 31(46), 6657-6660	
	13	Guerra et al., "Synthetic 6-Glucosyl Phospholipid as a Drug Transport System", <i>Tetra. Letters</i> , 1987 , 28(31), 3581-3584	
	14	Haralambidis et al., "The Solid Phase Synthesis of Oligonucleotides Containing a 3'-Peptide Moiety", <i>Tetra. Letters</i> , 1987 , 28(43), 5199-5202	
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	19	Lemairte et al., "Specific antiviral activity of a poly(L-lysine)-conjugated oligodeoxyribonucleotide sequence complementary to vesicular stomatitis virus N protein mRNA initiation site", <i>Proc. Natl. Acad. Sci. USA</i> , 1986 , 84, 648-652	
	20	Leonetti et al., "Biological Activity of Oligonucleotide-Poly(L-lysine) Conjugates: Mechanism of Cell Uptake", <i>Bioconj. Chem.</i> , 1990 , 1, 149-153	
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	21	Letsinger et al., "Cholesteryl-conjugated oligonucleotides: Synthesis, properties, and activity as inhibitors of replication of human immunodeficiency virus in cell culture", <i>Proc. Natl. Acad. Sci. USA</i> , 1989 , 86, 6553-6556	
	22	Manoharan et al., "2'-O- and 3'-O- Pyrimidine Aminotether-Containing Oligonucleotides: Synthesis and Conjugation Chemistry", <i>Tetra. Letters</i> , 1995 , 36(21), 3647-3650	
	23	Manoharan et al., "Lipidic Nucleic Acids", <i>Tetra. Letters</i> , 1995 , 36(21), 3651-3654	
	24	Miller et al., "A new approach to chemotherapy based on molecular biology and nucleic acid chemistry: Matagen (masking tape for gene expression)", <i>Anti-Cancer Drug Design</i> , 1987 , 2, 117-128	
	25	Nelson et al., "Bifunctional oligonucleotide probes synthesized using a novel CPG support are able to detect single base pair mutations", <i>Nucl. Acids. Res.</i> , 1989 , 17(18), 7187-7193	
	26	Ouchi et al., "Synthesis and Antitumor Activity of Poly(Ethylene Glycol)S Linked to 5-Fluorouracil Via a urethane or Urea Bond", <i>Drug Design and Disc.</i> , 1992 , 9, 93-105	
	27	Ramirez et al., "Nucleotidophospholipids: Oligonucleotide Derivatives with Membrane-Recognition Groups", <i>J. Am. Chem. Soc.</i> , 1982 , 104, 5483-5486	
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	29	Shea et al., "Synthesis, hybridization properties and antiviral activity of lipid-oligodeoxynucleotide conjugates", <i>Nuc. Acids Res.</i> , 1990 , 18(13), 3777-3783	
	30	Stepkowski et al., "Blocking of Heart Allograft Rejection by Intercellular Adhesion Molecule-1 Antisense Oligonucleotides Alone or in Combination with Other Immunosuppressive Modalities", <i>J. Immunol.</i> , 1994 , 5336-5346	
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	31	Stirchak et al., "Uncharged Stereoregular Nucleic Acid Analogues. 1. Synthesis of a Cytosine-Containing Oligomer with Carbamate Internucleoside Linkages", <i>J. Org. Chem.</i> , 1987 , 52, 4202-4206	
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	33	Veber et al., "Isonicotinyloxycarbonyl, a Novel Amino Protecting Group for Peptide Synthesis", <i>J. Org. Chem.</i> , 1977 , 42(20), 3286-3288	
	34	Wachter et al., "A simple and efficient procedure for the synthesis of 5'-aminoalkyl oligodeoxynucleotides", <i>Nucl. Acids Res.</i> , 1986 , 14(20), 7985-7994	
	35	Weller et al., "Molecular Modeling of Acyclic Polyamide Oligonucleotide Analogues", <i>J. Org. Chem.</i> , 1991 , 56, 6000-6006	
	36	Yamana et al., "Synthesis and Interactive Properties of an Oligonucleotide with Anthraquinone at the Sugar Fragment", <i>Bioconjugate Chem.</i> , 1990 , 1, 319-324	
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	38	Zuckerman et al., "Site-Selective Cleavage of RNA by a Hybrid Enzyme", <i>J. Am. Chem. Soc.</i> , 1988 , 110, 1614-1615	
	39	Ali et al., "Synthesis of extended carbamate and urea linked thymidine dimers," <i>Nucleosides & Nucleotides</i> , 1996 , 15(9), 1531-1543	
	40	Conibear et al., "Measurement of nucleotide exchange kinetics with isolated synthetic myosin filaments using flash photolysis," <i>FEBS</i> , 1996 , 380, 13-16	
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	41	Schirmeister et al., "The 2-(4-Nitrophenyl)ethoxycarbonyl(npeoc) and 2-(2,4-Dinitrophenyl)ethoxycarbonyl(dnpeoc) groups for protection of Hydroxy functions in ribonucleosides and 2'-deoxyribonucleosides," <i>Helv. Chim. Acta</i> , 1993 , 76, 385-400	
	42	Uhlmann, E. et al., "Antisense Oligonucleotides: A New Therapeutic Principle", <i>Chem. Revs.</i> , 1990 , 90(4), 544-584	
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U. S. PATENT DOCUMENTS							
Examiner Initial		Document No.	Date	Name	Class	Subclass	
	43	3,687,808	08/29/72	Merigan, Jr. et al.	195	28	
	44	4,469,863	09/04/84	Ts'o et al.	536	27	
	45	4,476,301	10/09/84	Imbach et al.	536	27	
	46	4,958,013	09/18/90	Letsinger	536	27	
	47	5,023,243	06/11/91	Tullis	514	44	
	48	5,034,506	07/23/91	Summerton et al.	528	391	
	49	5,130,302	07/14/92	Spielvogel et al.	514	45	
	50	5,134,066	07/28/92	Rogers et al.	435	91	
	51	5,138,045	08/11/92	Cook et al.	536	27	
	51	5,141,813	08/25/92	Nelson	428	402	
	52	5,166,195	11/24/92	Ecker	514	44	
	53	5,177,196	01/05/93	Meyer, Jr. et al.	536	22.1	
	54	5,212,295	05/18/93	Cooke	536	26.7	
	55	5,214,134	05/25/93	Weis et al.	536	25.3	
	56	5,216,141	06/01/93	Benner	536	27.13	
	57	5,223,618	06/29/93	Cook et al.	544	276	
	58	5,242,906	09/07/93	Pagano et al.	514	44	
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	59	5,248,670	09/28/93	Draper et al.	514	44	
	60	5,264,423	11/23/93	Cohen et al.	514	44	
	61	5,264,562	11/23/93	Matteucci	536	23.1	
	62	5,264,564	11/23/93	Matteucci	536	23.1	
	63	5,321,131	06/14/94	Agrawal et al.	536	25.34	
	64	5,359,044	10/25/94	Cook et al.	536	23.1	
	65	5,359,051	10/25/94	Cook et al.	536	26.7	
	66	5,378,825	01/03/95	Cook et al.	536	25.34	
	67	5,399,676	03/21/95	Froehler	536	23.1	
	68	5,405,939	04/11/95	Suhadolnik et al.	530	322	
	69	5,432,272	07/11/95	Benner	536	25.3	
	70	5,434,257	07/18/95	Matteucci et al.	536	24.3	
	71	5,442,049	08/15/95	Anderson et al.	536	24.5	
	72	5,455,233	10/03/95	Spielvogel et al.	514	44	
	73	5,457,187	10/10/95	Gmeiner et al.	536	25.5	
	74	5,457,189	10/10/95	Crooke et al.	536	24.5	
	75	5,457,191	10/10/95	Cook et al.	536	27.13	
	76	5,459,255	10/17/95	Cook et al.	536	27.13	
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	77	5,470,967	11/28/95	Huie et al.	536	24.3	
	78	5,484,908	01/16/96	Froehler et al.	536	24.31	
	79	5,489,677	02/06/96	Sanghvi et al.	536	22.1	
	80	5,495,009	02/27/96	Matteucci et al.	536	25.3	
	81	5,502,177	03/26/96	Matteucci et al.	536	26.6	
	82	5,506,351	04/09/96	McGee	536	55.3	
	83	5,510,239	04/23/96	Baracchini, Jr. et al.	435	6	
	84	5,514,577	05/07/96	Draper et al.	435	238	
	85	5,514,788	05/07/96	Bennett et al.	536	23.1	
	86	5,519,126	05/21/96	Hecht	536	24.3	
	87	5,519,134	05/21/96	Acevedo et al.	544	243	
	88	5,530,114	06/25/96	Bennett et al.	536	24.3	
	89	5,539,389	07/23/96	Bystrak et al.	340	825.52	
	90	5,541,307	07/30/96	Cook et al.	536	23.1	
	91	5,543,507	08/06/96	Cook et al.	536	23.1	
	92	5,576,925	11/19/96	Gorowitz et al.	361	301.2	
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	93	6,111,085	08/29/00	Cook et al.	536	22.1
	94	6,166,188	12/26/00	Cook et al.	536	4.1
	95	US 6,322,987 B1	11/27/01	Cook, et al.	435	6

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					YES	NO
	96	0 251 283 A2	01/07/86	EPO		
	97	WO 90/10448	09/20/90	PCT		
	98	WO 86/02929	05/22/86	PCT		

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